

## REMARKS/ARGUMENTS

In the light of the Final Rejection dated March 19, 2007 for the U.S. Patent Application 10/605, 577 filed on September 10, 2003 by applicant the applicants herein bring forth the following response for the said office action. New claims 18 and 19 are added to clarify the nature of the invention.

The examiner has predominantly cited two references US5972397 and US7063861 as the basis for the final rejection dated March 17, 2007. A closer look into the claims of each of these applications in relation to the legal definitions of the terms "cosmetic" and "drug" as defined by the Food, Drug and Cosmetic Act, U.S. Food and Drug Administration would help elucidate the basis of U.S. Patent Application 10/605, 577.

SEC. 201. [21 U.S.C. 321] (i) states that, The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

SEC. 201. [21 U.S.C. 321] (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement

is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

It is to be clearly understood from above that a cosmetic as such only enhances beauty, attractiveness and outward appearance. A cosmetic may also have properties of a drug. But in such a case, the term "cosmetic" cannot be singly used to describe the substance. Instead the substance may be defined as cosmetic/drug combination since it complies with the requirements of both "cosmetics" and "drugs". When the term "cosmetic" is singly used it must be construed to include only (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles.

It is also well known that an invention is best described by the claims and the claims must be supported by the Detailed Description with relevant examples that emphasize the statement of claims.

## ANALYSIS OF THE REFERENCES

I. US5972357-This patent has the following claims.

What is claimed is:

1. A cosmetic comprising a polyisoprenylated benzophenone derivative.

Applicant remarks : Cosmetic refers to an agent with no far reaching effects on the skin, unlike a medicament or drug.

2. The cosmetic of claim 1 wherein said polyisoprenylated benzophenone derivative is present in an amount from 0.00001% to 10% by weight.

3. The cosmetic of claim 1 wherein said polyisoprenylated benzophenone derivative is present in an amount from 0.001% to 5% by weight.
4. The cosmetic of claim 1 wherein said polyisoprenylated benzophenone derivative is an organic extract of a plant belonging to the Guttiferae (Hypericaceae) family.
5. The cosmetic of claim 1 wherein said polyisoprenylated benzophenone derivative is a garcinol.

Observations-Claims 1-5 are “just for cosmetics” which means the claims are to include only (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles. Since the term “cosmetic” is singly used the claims cannot be construed to include the properties of drugs as per the law. Further, the therapeutic effects as proved by examples in the patent have not been claimed. A detailed analysis of each of the examples herein below also illustrates how the terms “cosmetic” and “drug” are being interchangeably used in the patent.

Example 1-Health Drinks with extracts (can be interpreted as food as the drink is ingested)-90-450 mg of the polyisoprenylated benzophenone derivatives (garcinol and isogarcinol) can be ingested by drinking 100-1,000 g of the healthy drink per day.

Example 2- Healthy food (in the form of fine particles) with extracts

Example 3- Healthy food in the form of soft capsules with extracts

Example 4-Skin Cosmetics – applicants would like to point out that this description is not clearly defined, although it relates to skin care.

Example 5-Anti-ulcer syrup containing garcinol

Example 6- Anti-ulcer powder containing garcinol

Example 7- Anti-ulcer powder containing isogarcinol

The concluding paragraph in the text is very broad and mentions that polyisoprenylated benzophenone derivatives as the effective components of the present invention have various functions intimately relating to the maintenance of health, so that these derivatives can be used as foods and drinks, healthy foods, food additives or cosmetics as well as pharmaceuticals are extremely useful in industry.

General remarks-

1. Only cosmetic has been claimed. None of the claims can be construed to include drug properties and hence no therapeutic benefit to such cosmetics can be attributed.
2. Useful biological properties of such cosmetics are disclosed in the examples. However, nothing has been claimed. So the utility of such cosmetics for skin aging etc has not been claimed. It cannot be assumed to include such uses. Further, the Sabinsa application does not claim any of the biological properties mentioned in this patent. Thus Sabinsa is not infringing on any of the claims that has been mentioned in this reference.
3. Further, the term cosmetic can be interpreted as only “beauty or appearance” enhancers, as per the legal definition. The claims could be construed to encompass “beauty care” or “personal care” domains, but certainly “health care” benefits such as prophylactic/therapeutic benefits cannot be accepted in the light very broad, non-specific claims.

4. The claims are too broad. This is very advantageous for us to present our explanation. An explanation on the aforesaid grounds accompanied with appropriately modified claims should reasonably ensure the survivability and reexamination of the application.

## II. US7063861

This is exclusively a method of treatment patent. It is actually a method of “weight loss therapy” using HCA, garcinol in combination with anthocyanin. The therapeutic effect of the HCA, garcinol and Anthocyanin in combination has been implicated for its use in the therapeutic method. Note that the composition is not claimed. Further, the percentage of garcinol (0.01%-10%) is relative to the percentage of hydroxycitric acid. Garcinol does not exist singly.

A request for continued examination is filed along with this response. As the response is being filed after the expiration of the statutory period for response specified in the Office Action, applicants respectfully request an extension of time for response of three months for which the required fee is enclosed. Applicants respectfully request that this amendment be entered and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

SABINSA CORPORATION



By \_\_\_\_\_

Dr. Subbalakshmi Prakash  
VP Innovation & Business Development  
Tel: (732) 777 1111  
Registration No: 57192